

# **BROOKSTEIN DECLARATION**

## **EXHIBIT 16**

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 19/10/2000

SUBJECT : Polyester - Dyneema Braid

Dear Don,

Please find enclosed 4 DT trials samples for your inspection ,these have been made using Polyester/Dyneema mixed either in the cover or straight core, to match US2 I have set out below a matrix of how each was made and their results for your information

**DT PA23** SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER,  
STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c

COVER 16 carriers in use each with 1 end of 138 d'tex Polyester per carrier

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 38

Stage	St/pull kg	Knot/pull kg	Runnage mt/kg	Diameter mm	Extensin %	Solids %
M/c	19.12	9.87	3455	0.677	5.48	
Dye	17.05	8.81		0.589	10	
Stretch	16.51	6.95		0.577	5.3	15.3
Finish	17.2	10.35	3375	0.569	6.8	

DEPUY MITEK  
EXHIBIT 164  
04cv12457

PR 06515

Confidential - Outside Attorneys' Eyes Only

**DT PA25** SAMPLE COMMENTS: BOTH CORE AND COVER BROKE ON THE STRAIGHT PULL AT DYE STAGE, ON THE STRAIGHT PULL AT STRETCH STAGE THE CORE BROKE ONLY  
16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 poly 8 car with 1 end of 110 dyneema

CORE 1 end of 190/1/3 with 10 TPI "S" and 7 TPI "Z"

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	28.82	11.293	3803	0.582	11.15	
Dye	25.56	10.5		0.582	14.7	
Stretch at 5%	26.84	10.58		0.587	9.9	
Finish	24.35	11.95	3703	0.55	11.2	15.3

**DT PA26** SAMPLE COMMENTS: CORE BROKE IN FIRST TWO READINGS, WHOLE BRAID BROKE IN THIRD

16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 polyester 8 car with 1 end of 110 Dyneema

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	21.82	10.953	3908	0.681	5.28	
Dye	23.62	12.26		0.693	10.1	
Stretch at 5%	24.56	11.79		0.573	5.8	
Finish	21.48	12.87	3786	0.578	6	15.3

**DT PA27** SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY  
COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c

COVER 16 carriers in use

16 car with 1 end of 113 Polyester per carrier

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 44

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	19.14	9.037	4033	0.549	5.9	
Dye	16.18	8.35		0.548	8.5	
Stretch at 5%	16.49	6.54		0.545	5.5	
Finish	16.12	8.04	3919	0.553	5.6	15.3

If I can be of any further assistance please do not hesitate to contact me

Kind regards

**Brian Hallett**

Brian Hallett

Product Development Manager

# **BROOKSTEIN DECLARATION**

## **EXHIBIT 17**

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF MASSACHUSETTS

3 DePuy Mitek, Inc., a  
4 Massachusetts Corporation,

5 Plaintiff,

6 vs.

CIVIL ACTION  
7 NO. 04-12457 PBS

Arthrex, Inc., a Delaware  
8 Corporation,

9 Defendant.

10 DEPOSITION OF:

ASHLEY HOLLOWAY

11 DATE:

September 15, 2005

12 TIME:

1:08 p.m. to 5:07 p.m.

13 LOCATION:

The Ritz Carlton Golf Resort  
2600 Tiburon Drive  
Naples, FL 34112

14 TAKEN BY:

Plaintiff

15 REPORTER:

Deborah A. Krotz, RPR, CRR

16 VIDEOGRAPHER:

Les Smoak, CLVS

Condensed Copy

<p>1 suture --</p> <p>2 A. Correct.</p> <p>3 Q. -- with respect to knot security; is that right?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. Does Arthrex test its FiberWire sutures</p> <p>6 for pliability?</p> <p>7 A. No.</p> <p>8 Q. Do you know what pliability means?</p> <p>9 A. Pliability --</p> <p>10 Q. As it relates to FiberWire sutures?</p> <p>11 A. I don't know the exact definition, no.</p> <p>12 Q. But Arthrex does not test its FiberWire sutures</p> <p>13 for pliability?</p> <p>14 A. No.</p> <p>15 Q. Has it ever tested its FiberWire sutures for</p> <p>16 pliability?</p> <p>17 A. Not that I'm aware of.</p> <p>18 Q. Does Arthrex test its FiberWire sutures for</p> <p>19 handleability?</p> <p>20 A. Yes.</p> <p>21 Q. How does Arthrex test its FiberWire sutures for</p> <p>22 handleability?</p> <p>23 A. It's a subjective test.</p> <p>24 Q. What do you mean by that?</p> <p>25 A. I mean basically we give a piece of suture to a</p>	<p>30</p> <p>1 Q. What do you mean by that?</p> <p>2 A. I mean everything that's in that construct.</p> <p>3 Q. Contributes to the handleability of the suture?</p> <p>4 A. Yes.</p> <p>5 Q. What is the handleability of Arthrex's FiberWire</p> <p>6 suture?</p> <p>7 MR. TAMBURRO: Objection to form.</p> <p>8 A. Do you want me to give you a subjective answer?</p> <p>9 Q. Let me rephrase the question. Has Arthrex</p> <p>10 received feedback from surgeons on the handleability of</p> <p>11 Arthrex's FiberWire suture?</p> <p>12 A. Yes.</p> <p>13 Q. And what was the feedback that Arthrex received</p> <p>14 from surgeons on the handleability of Arthrex's FiberWire</p> <p>15 suture?</p> <p>16 A. That it's easy to utilize.</p> <p>17 Q. And what surgeons provided that feedback?</p> <p>18 A. I have heard Dr. Burkhardt say that.</p> <p>19 Q. Anyone else?</p> <p>20 A. Not directly to me, no.</p> <p>21 Q. Have any doctors provided negative feedback to</p> <p>22 Arthrex on the handleability of Arthrex's FiberWire</p> <p>23 suture?</p> <p>24 A. Yes.</p> <p>25 Q. How many doctors have provided negative feedback</p>
<p>31</p> <p>1 product manager or a surgeon who is familiar with the</p> <p>2 field of sutures and ask them to give us feedback on the</p> <p>3 handleability.</p> <p>4 Q. And what is handleability measured in?</p> <p>5 A. There are no units. It's subjective.</p> <p>6 Q. So what does "handleability" mean? What does the</p> <p>7 definition of "handleability" mean as Arthrex uses that as</p> <p>8 a test for its FiberWire sutures?</p> <p>9 A. What do I think it means?</p> <p>10 Q. What does Arthrex think it means?</p> <p>11 A. I think handleability as is it easy to move</p> <p>12 through the tissue or pass through the tissue? Is it easy</p> <p>13 to slide knots? Is it easy to tie knots?</p> <p>14 Q. Anything else?</p> <p>15 A. Is it easy to slide through the anchor eyelet?</p> <p>16 Q. Anything else?</p> <p>17 A. Not that I can think of.</p> <p>18 Q. Do materials contribute to the handleability of</p> <p>19 Arthrex's FiberWire sutures?</p> <p>20 MR. TAMBURRO: Objection to form.</p> <p>21 A. Yes.</p> <p>22 MR. TAMBURRO: Also, it's outside the scope.</p> <p>23 Q. What materials contribute to the handleability of</p> <p>24 Arthrex's FiberWire sutures?</p> <p>25 A. All materials used.</p>	<p>31</p> <p>1 to Arthrex on the handleability of Arthrex's FiberWire</p> <p>2 suture?</p> <p>3 A. I know of only one account.</p> <p>4 Q. And who was that?</p> <p>5 A. I believe, again, it might have been Dr.</p> <p>6 Burkhardt.</p> <p>7 Q. And what negative feedback did Dr. Burkhardt</p> <p>8 provide to Arthrex on the handleability of Arthrex's</p> <p>9 FiberWire sutures?</p> <p>10 A. That the nylon was too repetitive in the</p> <p>11 TigerWire.</p> <p>12 Q. What does that mean?</p> <p>13 A. It means there were too many wraps.</p> <p>14 Q. And that affected the handleability of the</p> <p>15 suture?</p> <p>16 A. That affected the feel.</p> <p>17 Q. Is the feel like handleability, or is that</p> <p>18 another word for handleability -- feel?</p> <p>19 A. Feel would fall under handleability; how does it</p> <p>20 feel in your hands.</p> <p>21 Q. All right. So that's one criteria used for the</p> <p>22 handleability?</p> <p>23 A. Right.</p> <p>24 Q. As well as passing the suture through tissue or</p> <p>25 any other things you described?</p>

# **BROOKSTEIN DECLARATION EXHIBIT 18**

1  
IN THE UNITED STATES DISTRICT COURT  
2 FOR THE MIDDLE DISTRICT OF MASSACHUSETTS

3 DEPUY MITEK, INC.,  
4 a Massachusetts corporation,

5 Plaintiff,

6 v.

Case No: CA-0412457-PBS

7 ARTHREX, INC, a  
Delaware corporation,

8 Defendant.

9  
10 VIDEOTAPE DEPOSITION OF ANN WATERHOUSE

11 TAKEN: Pursuant to Notice by  
12 Counsel for the Plaintiff

13 PLACE: Ritz Carlton Golf Resort  
2600 Tiburon Drive  
Naples, FL 34109

14 DATE: Wednesday, August 24, 2005

15 TIME: Began: 8:55 a.m.  
16 Ended: 1:00 p.m.

17 BEFORE: TRACIE L. MOUNTAIN-THOMPSON  
18 Court Reporter  
Notary Public  
State of Florida at Large

22 COPY  
23  
24  
25

Page 46

- 1 Q What does that mean?  
 2 A In the first paragraph, under suture  
 3 weight, which is coating, it says, "Pearsalls makes the  
 4 following statement about the NuSil coating applied to  
 5 both our Arthrex FiberWIRE and other competitive  
 6 product."

7 So they're demonstrating their processing of  
 8 that coating by the statement that follows.

- 9 Q That statement is from NuSil, not from Arthrex?  
 10 A No. That's from Pearsalls.

- 11 Q All right. But just to be clear, the coating  
 12 on the FiberWIRE product is MED-2174, right?  
 13 A Correct.

14 Q Okay. And in that last paragraph on page  
 15 2104, the second sentence says, "As noted (above) we  
 16 cannot measure the amount of coating so the product is  
 17 accepted by our customers on the basis of an agreed  
 18 detailed coating process which includes mixing the NuSil  
 19 to a certain viscosity and the speeds, temperatures, and  
 20 other parameters for the coating process. For each  
 21 coating batch all these details are recorded in the batch  
 22 documentation available to you and other customers."

23 Do you see that?

24 A Yes.

25 Q What does that mean?

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- 1 A Correct.  
 2 Q "We," Pearsalls, "cannot measure the amount of  
 3 coating so the product is accepted by our customers on  
 4 the basis of an agreed detailed coating process which  
 5 includes mixing the NuSil to a certain viscosity and the  
 6 speeds, temperatures and other parameters for the coating  
 7 process."

8 A Correct.

- 9 Q So does Arthrex accept batches of FiberWIRE  
 10 based on the coating?

11 MR. SABER: Objection. Vague. Confusing  
 12 question.

13 BY MR. FALKE:

- 14 Q All right. Was Pearsalls representing to  
 15 Arthrex that it cannot measure the amount of coating on  
 16 the FiberWIRE product when Arthrex submitted this  
 17 statement to the FDA in Exhibit 81?

18 A Can you repeat the question.

19 Q Sure.

- 20 Was Pearsalls representing to Arthrex that  
 21 Pearsalls cannot measure the amount of coating on the  
 22 FiberWIRE product when Arthrex submitted Exhibit 81 to  
 23 the FDA?

24 A Yes, as a percentage.

25 Q As a percentage of what?

Page 47

- 1 A That means that that's the processing that  
 2 they -- they put onto our product and it's describing  
 3 that they do it to a certain viscosity. They do it at a  
 4 certain speed and temperature. And they have other  
 5 parameters for the coating process. So that coating  
 6 process is an agreed upon process by their buyers,  
 7 basically, so that's what it is. That's how it's  
 8 actually done.

- 9 Q Does Arthrex and Pearsalls have an agreed -- an  
 10 agreed detailed coating process?

11 A Not that I know of.

- 12 Q So how does Arthrex know how the FiberWIRE  
 13 coating is applied to its FiberWIRE product?

- 14 A Specifically, they could ask for that batch  
 15 record for each lot that is produced, but in  
 16 general, they know the coating process because of the  
 17 temperature and speed, and the parameters that Pearsalls  
 18 uses coats that in an even manner, so it's an assumption.

- 19 Q Is it true that Pearsalls cannot measure the  
 20 amount of coating on the FiberWIRE product?

- 21 MR. SABER: Objection. Inconsistent with the  
 22 testimony.

23 BY MR. FALKE:

- 24 Q I'm just looking. It says -- on page 2104 it  
 25 says, "We," and I assume that's Pearsalls; is that right?

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- 1 A The total weight of the suture.  
 2 Q Has Arthrex submitted any document to the FDA  
 3 in any submission which details the coating process  
 4 Pearsalls uses to coat any FiberWIRE suture?

5 A No.

6 Q Why not?

- 7 A Because we used the statement as a reference  
 8 point so that we didn't have to submit anything about the  
 9 coating process. We described it instead.

- 10 Q You say "the statement," which statement is  
 11 that?

- 12 A On 2104, the statement that Pearsalls makes.

- 13 Q Okay. And then it says, in the last sentence  
 14 on page 2104, "For each coating batch all these details  
 15 are recorded in the batch documentation available to you  
 16 and other customers."

17 Do you see that?

18 A Yes.

- 19 Q Is the reference to "you" in that sentence.  
 20 does that refer to Arthrex?

21 A Correct.

- 22 Q Does Arthrex have any documents which reflect  
 23 the details of the coating process for the batches of  
 24 FiberWIRE it receives?

25 A Not that I know of.

13 (Pages 46 to 49)

1 Q Does Arthrex have the ability to obtain those  
2 documents?  
3 A Yes.  
4 Q So Pearsalls can determine the percentage --  
5 cannot determine the percentage of coating to the total  
6 weight of the suture; is that right?  
7 A Correct.

8 MR. SABER: Objection. Vague.  
9 BY MR. FALKE:

10 Q I'm sorry, what was your answer?  
11 A Correct.

12 Q And the reason they can't do that is because  
13 they can't measure the amount of coating on it;  
14 therefore, they can't measure the percentage of the  
15 amount of coating to the total weight, right?

16 A Correct.

17 Q I'm going to reask that question because the  
18 record is slightly unclear. So Pearsalls cannot  
19 determine the percentage of coating to the total weight  
20 of the suture; is that right?

21 MR. SABER: Could you read that question back,  
22 please.

23 (The court reporter read back the requested  
24 portion of testimony.)

25 MR. SABER: Objection. Vague. Asked and

1 Q What do you mean by "when tested"?  
2 A We test according to 10993, which is cited in  
3 that paragraph.  
4 Q Uh-huh.  
5 A There are certain tests that you have to  
6 perform according to that based on the use of your  
7 product. When they test that, as an example -- and  
8 you've got both of the tests -- they test whether there  
9 is a reaction or -- a negative reaction or an adverse  
10 reaction as opposed to nothing happening.

11 Q Right.  
12 A If it -- if there is nothing happening, they  
13 consider that pharmacologically inactive.

14 Q Has Arthrex made any representation to the FDA  
15 in any submission as to whether MED-2174 is absorbable in  
16 the body?

17 A No.

18 Q Do you know if MED-2174 is absorbable in the  
19 body?

20 A No.

21 Q No, you don't know?

22 A I don't know.

23 Q I think I asked this but I'm going to ask it  
24 again. And Exhibit 81 was submitted to the FDA by  
25 Arthrex, right?

1 answered.

2 BY MR. FALKE:

3 Q You can answer.

4 A Correct.

5 Q Okay. If you could turn to page 2130, please,  
6 in Exhibit 81.

7 I'm sorry, are you there?

8 A Uh-huh.

9 Q If you look at the last paragraph on that page,  
10 2130, and in particular, the last sentence, it says --  
11 excuse me, let me step back. The second to the last  
12 paragraph on page 2130, it says, in the last sentence of  
13 that paragraph, "The dyed polyester suture (D & C Blue  
14 No. 6) and di-peroxide silicone oil (coating) are  
15 pharmacologically inactive."

16 Do you see that?

17 A Yes, I do.

18 Q Does the di-peroxide silicone oil (coating)  
19 refer to the MED-2174 that's applied to the FiberWIRE  
20 product?

21 A Yes, it does.

22 Q And what does that mean "pharmacologically  
23 inactive"?

24 A Pharmacologically inactive means that it does  
25 not cause any reaction when tested.

1 A Yes, it was.

2 (Exhibit 82 was marked for identification.)

3 BY MR. FALKE:

4 Q Let me hand you Exhibit 82, which is a document  
5 with Bates numbers ARM001882 through 1884. Have you seen  
6 this document before?

7 A Yes, I have.

8 Q And what is Exhibit 82?

9 A This is the substantial equivalence letter for  
10 K010673.

11 Q And that reference, that K number, 010673,  
12 reverts to Exhibit 78, right?

13 A Correct.

14 Q And what is the purpose of this substantial  
15 equivalence letter, Exhibit 82?

16 A It's the FDA's way of granting you permission  
17 for sale of a product.

18 Q Okay. So through Exhibit 82 the FDA was  
19 granting Arthrex the permission to sell Arthrex  
20 FiberWIRE; is that right?

21 A Correct.

22 Q And Exhibit 82 is dated May 14th, 2001; is that  
23 right?

24 A Correct.

25 Q Did Arthrex sell FiberWIRE prior to May 14th,



# **BROOKSTEIN DECLARATION EXHIBIT 19**



April 26, 2001.

Food and Drug Administration  
Center for Devices and Radiological Health  
Attn: Mr. David Krause  
Department of Health and Human Services, Public Health Service  
Division of General & Restorative Devices  
9200 Corporate Boulevard  
Rockville, Maryland 20850

**RE: Amendment to Original Pre-Market Submission 510(k) #K010673,  
Arthrex FiberWIRE™**

On February 28, 2001 the Arthrex FiberWIRE™ was submitted to the FDA. Per a conversation between Ann Waterhouse (Arthrex) and David Krause (FDA) on April 16, 2001, the following is being sent as amendment information. Specifically included are percentages for content, labeling amendments, and research data for accessory equipment.

Arthrex has submitted in duplicate the requested information and respectfully asks that these be accorded the same confidentiality as the original submission, K010673. We request that the Food and Drug Administration keep confidential all information outside of the 510(k) summary and indications for use.

Should the following information be in any way deficient, please let us know. We will be happy to provide you with any missing details or information. Should you have further questions concerning the amendment we have submitted, please contact either Vernon Brown or Ann Waterhouse at (941) 643-5553. Thank you.

Sincerely,

Ann Waterhouse  
Regulatory Affairs Specialist

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PROSECUTION COUNSEL  
ONLY

ARM 002103

1. In many places in the document the suture is described as being composed of polyester and ultrahigh molecular weight polyethylene (UHMWPE). Please describe the polyester and indicate what percentage of the suture weight is UHMWPE. Also, what percentage of the weight of the suture is the dye and what percentage of the weight of the suture is the coating?

**Description of the polyester:**

The Polyester used by Pearsalls to produce Arthrex FiberWIRE™ is created from high tenacity filaments of Polyethylene Terephthalate. Specifically, this is type 712 polyester that is manufactured by KoSa GmbH & Co KG.

**% of the suture weight which is Ultra high molecular weight polyethylene:**

Broken into percentage, the Polyester is 38.09% of the suture input and the Polyethylene (UHMW) is 61.91%.

**Suture weight which is dye:**

In using an accepted dye, D&C Blue No. 6, neither Pearsalls nor Arthrex measured the percentage of weight which the suture gained by the dye process. Pearsalls certifies that the process with which they dye the polyester conforms with the 2.0 Cupric Sulfate listed in the USP Matching Solutions table on page 1585 of USP 24. Also, Pearsalls certifies to all of it's customers that the D&C Blue No. 6 is a FDA approved dye.

**Suture weight which is coating:**

Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE™ and other competitor product:

"The coating is a silicone rubber known as NuSil 2045. It is identical to the coating we apply for Davis & Geck silk suture, and is also used to coat "Ticron" polyester suture. As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."

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ARM 002104

2. You describe your suture as having a silicone elastomer coating. Please identify a legally marketed suture predicate that is coated with silicone.

The predicate devices with Nu-Sil silicone derivative or equivalent, used to coat silk and polyester suture are listed below. The 510 (k) summaries or statements for these predicate products are contained in the following pages:

K930586	Dermalon, Surgilon, Ophthalon, & Ophthalmic Suture
K930590	Silk Sutures
K961925	Polyester Non-Absorbable Surgical Suture
K990088	Synthofil Non-Absorbable PET Surgical Suture
K001172	Polyester Non-Absorbable Surgical Suture
K003590	Grams Polyester Non-Absorbable Suture

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ARM 002105

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# **BROOKSTEIN DECLARATION EXHIBIT 20**

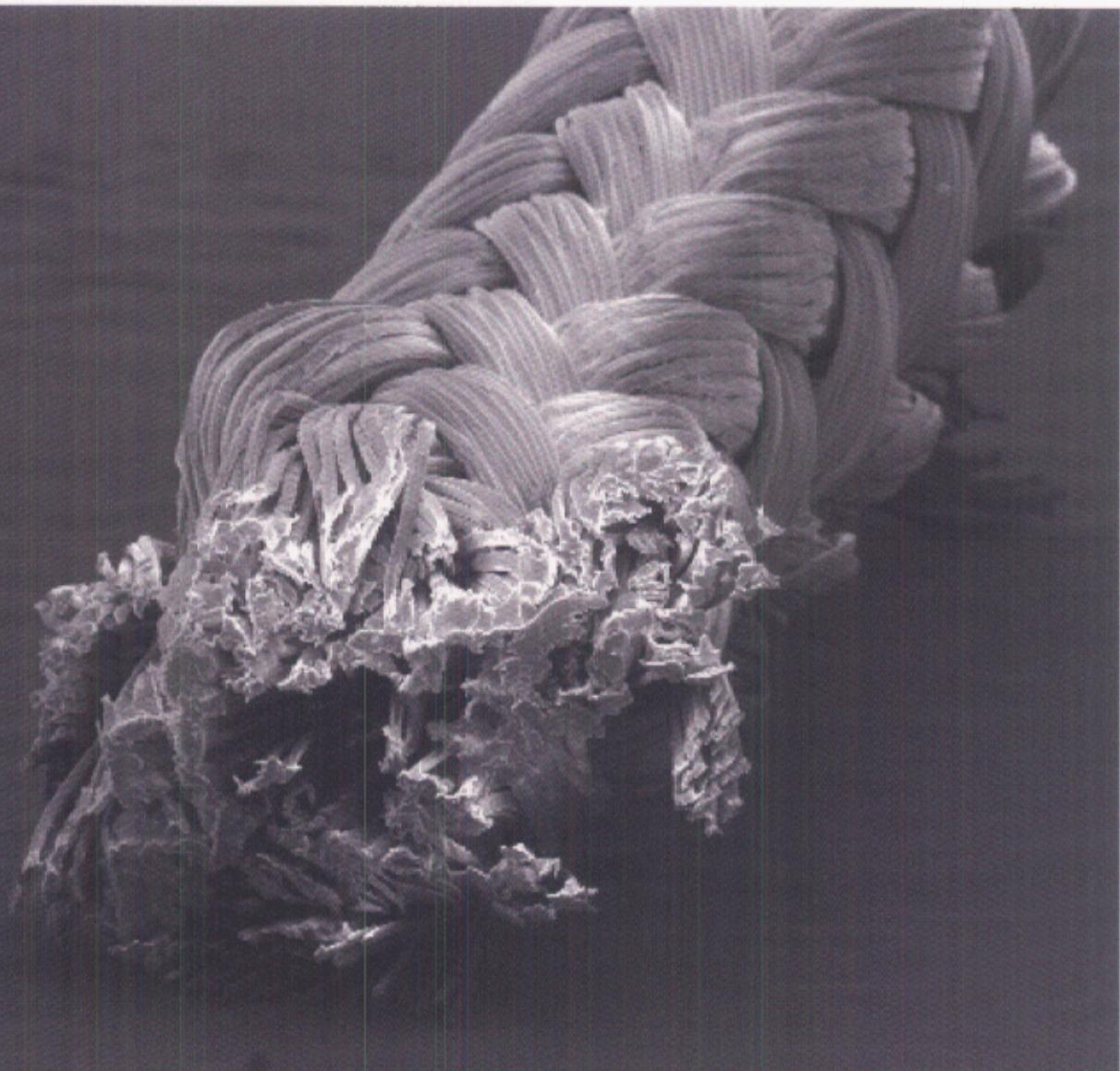


15KV

48x

208 μm 0000

# **BROOKSTEIN DECLARATION EXHIBIT 21**



15KV

48x

208 μm

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